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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,997	12/05/2001	John W. Sliwa	003-007-C4	5763

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/008,997

Applicant(s)

SLIWA ET AL.

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74 and 78081 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/29/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 29, 2004 has been entered.

Terminal Disclaimer

Applicant filed a terminal disclaimer for US Application Serial No. 10/029,889 with the RCE of April 29, 2004. However, the '889 application has since gone abandoned making the need for a terminal disclaimer moot.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74 and 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 74 is unclear with the recitation "each ablating element being activated to ablate tissue...". There is no specific structure provided for performing such a function,

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and the recitation is more indicative of a method step making the scope of the claim unclear. It is noted that applicant may wish to recite that the control system is programmed to control the ablating elements in the manner recited to therefore provide proper and clear structure/means for performing the recited function.

Claim Rejections - 35 USC § 103

Claims 74, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker et al ('084) in view of the teaching of Sherman et al ('280).

Acker et al discloses an ablation system which includes a catheter which includes a plurality of focused ultrasonic transducers (column 4, lines 36+). While Acker et al discloses a controller which may be used to change the focus of the ablation elements to different tissue depths (col. 4, lines 60-67), there is no specific disclosure of providing different frequencies to the ablation elements.

Sherman et al provide an analogous ablation system which uses ultrasonic transducers to ablate cardiac tissue. In particular, Sherman et al specifically disclose a controller which provides the ablation elements with multiple frequencies over a plurality of time periods in order to arrive at the optimum frequency.

To have provided the Acker et al system with a means to vary the frequency delivered by the transducers over a given time period to arrive at the optimal frequency would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sherman et al.

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Claims 80 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acker et al and Sherman et al as applied to claims 74, 78 and 79 above, and further in view of the teaching of Marcus et al ('484).

The combination of the Acker et al and Sherman et al teachings has been addressed previously. These references fail to specifically disclose a means for sensing the adequacy of contact between the ablating elements and the tissue.

Marcus et al discloses another cardiac ablation apparatus which utilizes ultrasonic energy to ablate tissue. Marcus et al further specifically teach that it is advantageous to provide a means to assess tissue contact between the ablating elements and tissue to ensure the ablating elements are properly oriented (col. 4, lines 64-68).

To have provided the Acker et al system, as modified by the teaching of Sherman et al, with a means to determine tissue contact to ensure the ablating elements are properly oriented would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Marcus et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74 and 78-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/255,134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the specific focusing of the ablating elements is deemed an obvious characteristic of the system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed April 29, 2004 have been fully considered but they are not persuasive.

Applicant contends that the combination of the Acker and Sherman references does not disclose or suggest a control system "adapted to automatically change the frequency of the ablating elements when ablating the same tissue structure". The examiner disagrees.

As pointed out by applicant, Sherman sweeps through a range of frequencies to locate a center operational frequency which is used to ablate tissue (applicant's response, page 3, paragraph 4). That operational frequency is then used to ablate tissue, and the controller may be used to automatically and periodically sweep the frequencies to recalibrate the center frequency (col. 17, lines 22-38 of Sherman). The examiner maintains that this recitation meets the limitations of claim 74. In particular,

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after establishing the operational frequency (i.e. "the first frequency"), tissue is ablated. The controller at some later time sweeps the frequency which may then yield a second frequency, different from the first, which is used to continue the ablation process. Hence, the frequency is changed from a first to a second frequency at two (or more) different time periods. Hence, the Sherman controller is clearly adapted to delivery various ultrasonic frequencies at various time periods throughout an ablation procedure.

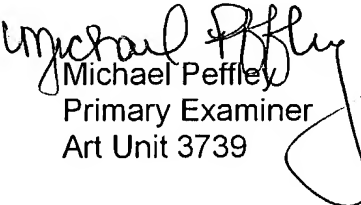
With regard to the previous double patenting rejection with US Application Serial No. 10/028,889, it was discovered that the '889 application has gone abandoned making the double patenting rejection moot. The examiner has discovered a new application, US Application Serial No. 10/255,134 which is deemed to contain claims that present additional double patenting issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
June 4, 2004